REMARKS

This Response is to the non-final Office Action dated September 11, 2009. Applicants believe that no fees are due with this Response, however, the Commissioner is hereby authorized to charge any fees that may be required or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712044-00439 on the account statement.

Claims 1 to 61 are pending in this application with Claims 27 to 61 having been previously withdrawn. In the Office Action, Claims 1, 2, 4, 8, 9 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,269,708 to Bonomini ("*Bonomini*"); Claims 3 and 5 to 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 3,669,880 to Marantz et al. ("*Marantz*"); Claims 10, 11, 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 4,229,299 to Savitz et al. ("*Savitz*"); Claims 12, 15 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 4,765,907 to Scott et al. ("*Scott*"); Claims 14, 16, 17 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 5,944,684 to Roberts et al. ("*Roberts*"); Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 5,685,989 to Krivitski et al. ("*Krivitski*"). Claims 22 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Publication No. 2005/0102028 to Laroche et al. ("*Laroche*"); Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Bonomini* in view of U.S. Patent No. 4,267,040 to Schal. ("*Schal*").

In response to the anticipation rejection of Claims 1, 2, 4, 8, 9 and 13, Applicants respectfully submit that *Bonomini* fails to disclose or suggest each and every element of the present claims. Currently amended independent Claim 1 recites, in part, a system for providing dialysis comprising a patient fluid loop including a first pump and multiple patient lumens, and a second fluid loop including a second pump, a medical fluid regenerator, and a gas separator that separates gases from the second fluid loop. The amendment does not add new matter and is supported in the specification at, for example, page 18, line 16 to page 19, line 31. Such a configuration provides unexpected clinical advantages (e.g., improved fluid volume control, higher efficiency, etc.), economic advantages (e.g., reduced therapy cost, etc.) and quality of life

advantages (e.g., reduced therapy training, reduced abdominal pressure caused by gas, etc.). See, specification, page 12, line 29 to page 13, line 22.

For example, the specification discusses problems caused by the carbon dioxide gases released by a sorbent cartridge present in the regeneration unit of the dialysis system. The present disclosure clearly explains that the sorbent cartridge in the second fluid loop may produce carbon dioxide and introduce the carbon dioxide gas into the second fluid loop, which may eventually enter into the patient fluid loop. Additionally, the user may even produce carbon dioxide and introduce the carbon dioxide into the loop. See, specification, page 18, line 16 to page 19, line 31. For at least these reasons, it is highly desirable to remove any gases from at least the regeneration loop, which includes the sorbent cartridge, to ensure that the system is safe and accurate and can be used by the patients continuously in a home environment while the patient sleeps. Accordingly, it would be clear to the skilled artisan that the configuration of the present claims provides unexpected clinical advantages, economic advantages and quality of life advantages that are not recognized by the prior art.

Additionally, Applicants also submit that *Savitz* fails to remedy the deficiencies of *Bonomini* since *Savitz* also fails to disclose or suggest a system for providing dialysis comprising a patient fluid loop including a first pump and multiple patient lumens, and a second fluid loop including a second pump, a medical fluid regenerator, and a gas separator that separates gases from the second fluid loop. As discussed in the Amendment dated April 30, 2009, *Savitz* does not disclose two fluid loops separated by a membrane device in fluid contact with both loops. Instead, *Savitz* merely discloses alternative dialysis fluid supply embodiments (column 5, lines 30 to 32), as is clearly shown by Figure 1 of *Savitz*, which is reproduced below.

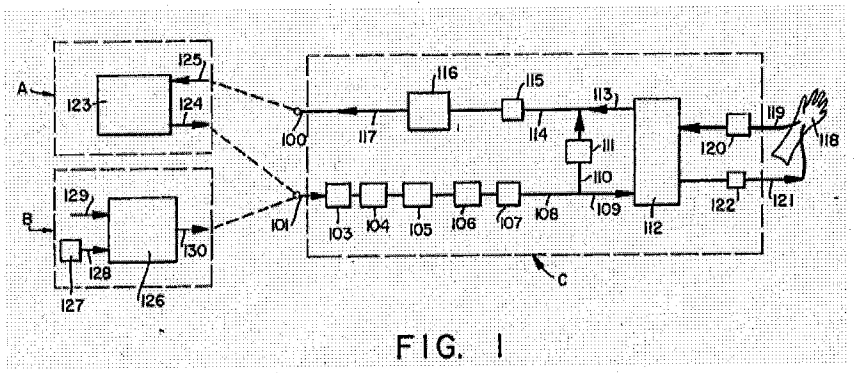

FIG. 1

Savitz discloses at column 5, line 25 to column 6, line 5, that there are three main portions "A", "B" and "C" to the system as shown above. Portion "C" is the hemodialysis portion having pump 116 and a dialyzer 112. Portion "C" is used regardless of whether Portion "A" or Portion "B" is used, however only one of Portion "A" or Portion "B" is used in a given treatment (column 6, lines 5 to 8). That is, Portions "A" and "B" are alternative dialysis fluid supply embodiments (column 5, lines 30 to 32). Portion "A" is a batch supply, while Portion "B" is an on-line supply, which makes the dialysis solution as it is being used from continuous water line 129, and not beforehand as with batch Portion "A". Because the online supply portion "B" can make as much dialysis fluid as needed (until concentrate 127 runs out), the system using supply Portion "B" dumps spent dialysis fluid or effluent to drain. That is, the dialysis fluid makes only a single pass through dialyzer 112 (column 5, lines 61 to 64).

With batch supply portion "A", the dialysis solution volume is limited, so it must be re-used or recirculated past the dialyzer 112 in a closed loop (column 5, lines 39 to 47) to achieve better patient clearance. But there is no disclosure that *Savitz* is regenerating the fluid in dialysate container 123. Instead, it appears that the batch dialysate is simply being reused until there is no osmotic gradient left between the dialysate and the patient's blood.

Additionally, the presently claimed system includes a pump in the second medical fluid regenerator loop. *Savitz*, on the other hand, appears to rely on pump 116 to drive dialysis fluid through both the hemodialysis portion "C" and the batch supply portion "A". There is no disclosure of a pump with supply portion "A" taught at column 5, lines 40 to 47 cited in the Office Action. Accordingly, it is clear that *Savitz* fails to disclose a second fluid loop including a second pump and a medical fluid regenerator, let alone a gas separator that separates gases from the second fluid loop. For at least the above-mentioned reasons, *Bonomini* fails to anticipate the present claims. Further, the combination of *Bonomini* and *Savitz* fails to meet the claims.

Regarding Claims 8 and 10, Applicants respectfully submit that neither *Bonomini* or *Bonomini* in view of *Savitz* disclose or suggest the use of either a) a single gas separator that separates gases from both patient and second fluid loops (as in Claim 10), or b) gas separators in each of the patient fluid loop and the second fluid loop (as in Claim 8). Such configurations advantageously remove gases (e.g., air, carbon dioxide) that are entrained in the patient fluid loop and the second fluid loop. Specifically, the present disclosure solves the problem caused by the carbon dioxide gases released by a sorbent cartridge present in the regeneration unit of the

dialysis system. The present disclosure clearly explains that the sorbent cartridge in the second fluid loop may produce carbon dioxide and introduce the carbon dioxide gas into the second fluid loop, which may eventually enter into the patient fluid loop. See, specification, pages 18 to 19.

Further, the inability of *Bonomini,* or even *Bonomini* and *Savitz*, to teach Claim 1 renders moot whether or not: (i) *Bonomini* and *Marantz* additionally teaches dependent Claims 3 and 5 to 7; (ii) *Bonomini* and *Savitz* teach Claims 11, 18 and 19; (iii) *Bonomini* and *Scott* teach Claims 12, 15 and 25; (iv) *Bonomini* and *Roberts* teach Claims 14, 16, 17 and 26; (v) *Bonomini* and *Krivitski* teach Claims 20 and 21; (vi) *Bonomini* and *Laroche* teach Claims 22 and 23; and (vii) *Bonomini* and *Schal* teach Claims 20 and 21.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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